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IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JULIE CRUZ and RAY CRUZ,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC.;
ETHICON, INC.; and COLOPLAST
CORP,

Defendants.

Case No. 8:18-cv-01539-JVS-JDE

**PLAINTIFFS' OPPOSITION TO
DEFENDANT COLOPLAST'S
MOTION TO DISMISS**

F.R.C.P. 12(b)(6)

Date: December 10, 2018

Time: 1:30 p.m.

Judge: Hon. James V. Selna

Crtrm: Santa Ana 10C

Complaint Filed: 08/28/18

First Amended Complaint Filed: 10/24/18

Trial Date: Not Set

I.

INTRODUCTION

Defendant Coloplast Corporation ("COLOPLAST") knowingly and intentionally manufactured and marketed a defective product. This product, Restorelle® Y Polypropylene Mesh was implanted in Plaintiff Julie Cruz ("CRUZ"). Although COLOPLAST knew that this product was unsafe, it marketed the product to plaintiff and represented that it was safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence. Not only was the product not safe and effective as presented, it penetrated CRUZ's vaginal wall,

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1 which lead to excision of the mesh via surgery. CRUZ continues to have pain and could be
2 subjected to additional surgeries to excise additional mesh.

3 COLOPLAST knew that this product was not safe when the FDA issued a Safety
4 Communication in 2011 and stated that “serious complications associated with surgical mesh for
5 transvaginal repair of POP (pelvic organ prolapse) are not rare.” (First Am. Compl. ¶66.)
6 Contemporaneously with this safety communication, the FDA also released a publication (“FDA
7 White Paper”) which stated that patients who undergo POP repair with mesh are subject to
8 mesh-related complications that are not experienced by patients who undergo traditional surgery
9 without mesh. (First Am. Compl. ¶70.) The FDA White Paper also stated that the products are
10 associated with serious adverse events and reiterated concerns that the data fails to demonstrate
11 improved clinical benefit over traditional non-mesh repair. (First Am. Compl. ¶72.) The FDA
12 White Paper concluded that it “has identified serious safety and effectiveness concerns over the
13 use of surgical mesh for the transvaginal repair of pelvic organ prolapse.” (First Am. Compl.
14 ¶74.)

15 II.

16 LEGAL ARGUMENT

17 A. Pleading with Specificity Pursuant to Rule 9(b)

18 Rule 9(b) of the Federal Rules of Civil Procedure requires that a plaintiff alleging a fraud
19 cause of action plead the cause of action with specificity. It states as follows,

20 “(b) FRAUD OR MISTAKE; CONDITIONS OF MIND. In alleging fraud or
21 mistake, a party must state with particularity the circumstances constituting fraud
22 or mistake. Malice, intent, knowledge, and other conditions of a person’s mind
may be alleged generally.” (Fed. R. Civ. P. 9(b).)

23 However, under Rule 9(b)’s heightened standard, a complaint need only plead facts
24 establishing fraud is plausible, not “probable.” (*Loreley Financing (Jersey) No. 3 Ltd. v. Wells*
25 *Fargo Securities, LLC*, 797 F3d 160, 175 (2nd Cir. 2015).); (SCHWARZER ET AL., FEDERAL CIVIL
26 PROCEDURE BEFORE TRIAL, §8:157 (Rutter Group 2018).) Although the identity of the person
27 who made the fraudulent representation is ordinarily required when pleading a fraud cause of
28 action, this may be excused where it is unrealistic to expect plaintiff to have this information.

1 For example, where fraud is claimed in a consumer transaction that occurred many months
 2 previously, the complaint need not name the store employee who made the misrepresentation.
 3 (*Odom v. Microsoft Corp.*, 486 F3d 541, 554-555 (9th Cir. 2007); (SCHWARZER ET AL., FEDERAL
 4 CIVIL PROCEDURE BEFORE TRIAL, §8:174 (Rutter Group 2018).)

5
 6 **B. The Fraud Based Causes of Action Have Been Specifically Plead Pursuant to
 Federal Rule of Civil Procedure 9(b).**

7 In this case, CRUZ has alleged within paragraph 53 of the First Amended Complaint that
 8 “Plaintiff and her physician, either through direct promotional contact with Coloplast Sales
 9 Representatives, Lab Faculty, through word-of-mouth with other healthcare providers, and/or
 10 through promotional materials, received the information Coloplast intended Plaintiff and her
 11 physician to receive and/or view, claiming that the Restorelle® Y Polypropelene Mesh was safe
 12 and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.”
 13 (First Am. Compl. ¶53.) This language is sufficient for specificity purposes. This is especially
 14 true when considered with the exceptions for specific pleading where it is clear from the pleading
 15 that certain information is within the exclusive knowledge of the defendants.

16 There are certain exceptions which mitigate the rigor of the rule requiring specific
 17 pleading of fraud. Less specificity is required when “it appears from the nature of the allegations
 18 that the defendant must necessarily possess full information concerning the facts of the
 19 controversy,” (*Bradley v. Hartford Acc. & Indem. Co.* 30 Cal.App.3d 818, 825 (1973).); “[e]ven
 20 under the strict rules of common law pleading, one of the canons was that less particularity is
 21 required when the facts lie more in the knowledge of the opposite party” (*Turner v. Milstein*
 22 103 Cal.App.2d 651, 658 (1951).; *Comm. On Children’s Television, Inc. v. Gen. Foods Corp.*, 35
 23 Cal. 3d 197, 217 (1983).) The identity of the COLOPLAST agents is within the exclusive
 24 control of COLOPLAST (a corporate defendant) and there has not yet been any discovery in this
 25 matter. Based thereon, the pleading is sufficient at this stage of the litigation.

26 **1. Fraudulent Concealment**

27 The elements of a claim for fraudulent concealment require the plaintiff to show that:
 28 “(1) the defendant ... concealed or suppressed a material fact, (2) the defendant [was] under a

duty to disclose the fact to the plaintiff, (3) the defendant ... intentionally concealed or suppressed the fact with the intent to defraud the plaintiff, (4) the plaintiff [was] unaware of the fact and would not have acted as he did if he had known of the concealed or suppressed fact, and (5) as a result of the concealment or suppression of the fact, the plaintiff must have sustained damage.” (*Marketing West, Inc. v. Sanyo Fisher (USA) Corp.* 6 Cal.App.4th 603, 612-613 (1992).) The duty to disclose may be established where there is a confidential relationship between the parties, defendant has made a representation which was likely to mislead due to the nondisclosure, there is active concealment of undisclosed matters, or one party has sole knowledge of or access to material facts and knows such facts are not known to or discoverable by the other party. (*Goodman v. Kennedy* 18 Cal.3d 335, 346-347 (1976); *Prakashpalan v. Engstrom, Lipscomb & Lack*, 223 Cal. App. 4th 1105, 1130 (2014).)

CRUZ has specifically pleaded all the necessary information for its claim. The complaint alleges with specificity that the FDA issued safety communications and publications which affirmatively stated that the product was not safe and effective for its intended use. (See First Am. Compl. ¶¶66-74, 120-122, 127-130.) It also alleges that COLOPLAST knew this information (First Am. Compl. ¶¶75-76, 83, 99-100, 128-130.) Finally, CRUZ alleges that she has sustained harm as a result of the concealment. (First Am. Compl. ¶¶131-133.) To the extent that the Court requires that a transactional relationship exist for this claim or any of the other fraud claims subject to this motion, that issue is addressed in section II(C) below.

2. Constructive Fraud

Constructive fraud “arises on a breach of duty by one in a confidential or fiduciary relationship to another which induces justifiable reliance by the latter to his prejudice.” (*Odorizzi v. Bloomfield School Dist.* 246 Cal.App.2d 123, 129 (1966); *Tyler v. Children’s Home Soc’y*, 29 Cal. App. 4th 511, 548 (1994).) CRUZ has specifically plead the elements of such a claim. As set forth below in section II(C), the relationship necessary for such a claim is sufficient between a buyer (CRUZ) and seller (COLOPLAST). Paragraphs 131 through 133 of the First Amended Complaint, and 140 through 144 set forth the facts demonstrating that CRUZ relied on the representations of COLOPLAST that the medical device was safe and effective for

its intended use and that she sustained damages in reliance on those representations by enduring health care and services and incurring medical, health, incidental and related expenses.

3. Negligent Misrepresentation

The elements of negligent misrepresentation are: (1) a misrepresentation of a past or existing material fact, (2) made without reasonable ground for believing it to be true, (3) made with the intent to induce another's reliance on the fact misrepresented, (4) justifiable reliance on the misrepresentation, and (5) resulting damage. (*Wells Fargo Bank, N.A. v. FSI, Financial Solutions, Inc.* 196 Cal.App.4th 1559, 1573 (2011); *National Union Fire Ins. Co. of Pittsburgh, PA v. Cambridge Integrated Services Group, Inc.* 171 Cal.App.4th 35, 50, (2009); *Ragland v. U.S. Bank Nat'l Assn.* 209 Cal. App. 4th 182, 196 (2012).)

CRUZ has adequately plead its negligent misrepresentation claim. She alleges that COLOPLAST misrepresented the safety and effectiveness of its product, even after being advised that the product was not safe for its intended use. (First Am. Compl. ¶¶53, 66-84, 98-100). She has also adequately alleged that she relied on such misrepresentations and that she was damaged as a result of such reliance. (First Am. Compl. ¶¶131, 132.)

C. CRUZ Has Plead Facts Which Give Rise to a Duty to Disclose Within the Fraud Causes Of Action.

COLOPLAST argues that there must be a fiduciary or transactional relationship in order to state a claim for concealment. However, a fiduciary or transactional relationship is not required to state such a claim. As set forth within *Warner Constr. Corp. v. City of Los Angeles* 2 Cal.3d 285, 294 (1970), "In transactions which do not involve fiduciary or confidential relations, a cause of action for non-disclosure of material facts may arise in at least three instances: (1) the defendant makes representations but does not disclose facts which materially qualify the facts disclosed, or which render his disclosure likely to mislead; (2) the facts are known or accessible only to defendant, and defendant knows they are not known to or reasonably discoverable by the plaintiff; (3) the defendant actively conceals discovery from the plaintiff." Indeed, California Civil Code section 1710 which defines deceit also confirms that such a relationship is not required for a concealment claim. It provides as follows:

1 “DECEIT, WHAT. A deceit, within the meaning of the last section,
2 is either:

- 3 1. The suggestion, as a fact, of that which is not true, by one who does not believe
4 it to be true;
- 5 2. The assertion, as a fact, of that which is not true, by one who has no
6 reasonable ground for believing it to be true;
- 7 3. The suppression of a fact, by one who is bound to disclose it, or who gives
8 information of other facts which are likely to mislead for want of
9 communication of that fact; or,
- 10 4. A promise, made without any intention of performing it.”

11 (Cal. Civ. Code 1710.)

12 Nevertheless, CRUZ has plead that COLOPLAST provided her with information, through
13 a COLOPLAST sales representative and/or their marketing material about the safety and
14 effectiveness of their product. However, COLOPLAST failed to provide information regarding
15 the safety risks and lack of effectiveness over traditional surgery of which they were aware. (See
16 First Am. Compl. ¶¶52, 53, 59, 66-74, 83-84, 121-122, and 127-133.)

17 If there is a relationship required, it certainly does not need to be a fiduciary relationship.
18 Neither constructive fraud nor concealment require a fiduciary relationship. A relationship need
19 not be a fiduciary one in order to give rise to constructive fraud. Constructive fraud also applies
20 to nonfiduciary “confidential relationships.” (*Odorizzi v. Bloomfield School Dist.*, *supra*, 246
21 Cal.App.2d at p. 129, 54 Cal.Rptr. 533.) “Such a confidential relationship may exist whenever a
22 person with justification places trust and confidence in the integrity and fidelity of another.”
23 (Ibid., [bare allegation of employer-employee relationship insufficient to support confidential
24 relationship].) “ ‘A confidential relation exists between two persons when one has gained the
25 confidence of the other and purports to act or advise with the other’s interest in mind. A
26 confidential relation may exist although there is no fiduciary relation ...’ ” (*Davies v. Krasna*
27 (1975) 14 Cal.3d 502, 510, 121 Cal.Rptr. 705, 535 P.2d 1161 [dictum]; *Tyler v. Children’s Home*
28 *Soc’y*, 29 Cal. App. 4th 511, 549, 35 Cal. Rptr. 2d 291, 313 (1994).)

It is clear from the allegations of the First Amended Complaint that CRUZ has plead
there was a confidential relationship between herself and COLOPLAST. She has plead that she
received information through Coloplast Sales Representatives and/or through its promotional
materials that the product was safe and effective for use in the treatment of pelvic organ prolapse

1 and stress urinary incontinence. (First Am. Compl. ¶53.) Moreover, COLOPLAST admits that
 2 all that is required is a transactional relationship between the parties. (Motion to Dismiss, 6:7-9.)

3 The case of *Bigler-Engler v. Breg, Inc.* 7 Cal.App.5th 276 (2017) also addressed this
 4 issue in the context of an intentional concealment claim. *Bigler* involved a case where a patient
 5 brought an action against a medical device manufacturer (Breg) for breach of fiduciary duty and
 6 intentional concealment claims, among others. There was an award in plaintiff's favor in the trial
 7 court on these claims. Berg appealed from the judgment against it. One of the bases for appeal
 8 was whether the evidence supported the jury's verdict against it for intentional concealment in
 9 the absence of a transactional relationship between Breg and Engler. The court set forth the
 10 elements for intentional concealment as follows: (1) the defendant must have concealed or
 11 suppressed a material fact; (2) the defendant must have been under a duty to disclose the fact to
 12 the plaintiff; (3) the defendant must have intentionally concealed or suppressed the fact with the
 13 intent to defraud the plaintiff; (4) the plaintiff must have been unaware of the fact and would not
 14 have acted as he did if he had known of the concealed or suppressed fact; and (5) as a result of
 15 the concealment or suppression of the fact, the plaintiff must have sustained damage
 16 (*Bigler-Engler v. Breg, Inc.* 7 Cal.App.5th 276 (2017) p. 311). On appeal, Breg argued that the
 17 second element (a duty to disclose) was absent because there was no transactional relationship
 18 between Engler and Breg. In *LiMandri v. Judkins* 52 Cal.App.4th 326 (1997), which is discussed
 19 in *Bigler*, the Court of Appeal explained that there are "four circumstances in which
 20 nondisclosure or concealment may constitute actionable fraud: (1) when the defendant is in a
 21 fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of
 22 material facts known to the plaintiff; (3) when the defendant actively conceals a material fact
 23 from the plaintiff; and (4) when the makes partial representations but also suppresses some
 24 material facts." (*LiMandri v. Judkins* 52 Cal.App.4th 326, 336 (1997).)

25 The court in *Bigler* went on to state, "A duty to disclose facts arises only when the parties
 26 are in a relationship that gives rise to the duty, such as 'seller and buyer', employer and
 27 prospective employee, doctor and patient, or parties entering into any kind of contractual
 28 arrangement.'" (*Bigler-Engler v. Breg, Inc.* 7 Cal.App.5th 276, 311 (2017).) Although the facts

of *Breg* were somewhat different in that there was no allegation that Breg received any statements from Bigler, the allegations of this complaint allege that there were statements made by COLOPLAST to CRUZ (First Am. Compl. ¶53.) Therefore, CRUZ has established the requisite relationship required, if any.

D. In the Event That The Motion to Dismiss is Granted, Leave to Amend Should be Granted.

Leave to amend is “almost always” allowed to cure deficiencies in pleading fraud. (*Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986.) Indeed, “[A] district court should grant leave to amend. . . unless it determines that the pleading could not possibly be cured by the allegation of other facts.” (*Cook, Perkiss & Liehe v. N. Cal. Collection Serv.*, 911 F.2d 242, 247 (9th Cir. 1990).) In the event that the Court intends to grant COLOPLAST’s Motion to Dismiss, CRUZ respectfully requests leave to amend.

III.

CONCLUSION

If the Court were to adopt COLOPLAST’s theory and reasoning, a medical device manufacturer could make fraudulent statements and never be subject to liability for fraud or punitive damages because they rarely interact directly with the patients. Nevertheless, CRUZ has demonstrated that she has plead her claims with the specificity required pursuant to Rule 9(b) of the Federal Rules of Civil Procedure and that she has established any required relationship between her and Coloplast. Based thereon, COLOPLAST’s Motion to Dismiss should be denied. In the event that it is granted, CRUZ respectfully requests that the Court grant her leave to amend her claims.

DATED: November 19, 2018

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CERTIFICATE OF SERVICE

The undersigned counsel for Plaintiffs hereby certifies that a true and correct copy of the foregoing documents was filed with the Court and served electronically through the CM-ECF (electronic case filing) system to all counsel of records to those registered to receive Notice of Electronic Filing for this case on November 19, 2018.

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